BROOKHAVEN NATIONAL LABORATORY

CLINICAL RESEARCH CENTER
POLICY MANUAL

PREPARED BY: _____

REVIEWED BY: _____
W. GUNTHER – CRC MANAGER

APPROVED BY: _____
G.J. WANG – MEDICAL DEPT. CHAIRMAN

EFFECTIVE DATE: _____

BROOKHAVEN NATIONAL LABORATORY

PRINCIPAL INVESTIGATOR MANUAL

ATTACHMENT B

PREPARED BY: _____

REVIEWED BY: _____
W. GUNTHER – CRC MANAGER

APPROVED BY: _____
G.J. WANG – MEDICAL DEPT. CHAIRMAN

EFFECTIVE DATE: _____

CLINICAL RESEARCH CENTER POLICY	PREPARED BY:
	REVIEWED BY :
SUBJECT: Description and Structure of the Clinical Research Center	APPROVED BY:
	EFFECTIVE DATE: 5/1/00

1.0 CLINICAL RESEARCH CENTER

The Clinical Research Center (CRC) is empowered by the Director of BNL through the SPI 7-01. The CRC has the responsibility to provide clinical support and oversight for studies involving human subjects. The CRC has the responsibility to provide an environment in which human research studies (or specialized programs providing clinical care) can be conducted in a manner compliant with the federal guidelines in 10 CFR 745 and provide a level of care commensurate with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards. All personnel working with human subjects need to have their credentials and training status reviewed and approved through the CRC prior to working with human subjects.

2.0 OPERATONAL AND MANAGEMENT

2.1 The operations and management of the Clinical Research Center are the responsibility of the Medical Department Chairperson. See Laboratory Organizational Chart (Attachment A).

2.2 The Medical Department Chairperson shall appoint a Clinical Research Advisory Board to assist him/her in operating and managing the CRC.

2.3 Clinical Research Advisory Board:
The Advisory Board shall be appointed by and report to the Chairperson of the Medical Department.

The Advisory Board shall have the following charge:

i. To oversee a comprehensive self-assessment plan.
ii. To advise the Chairperson regarding the implementation of clinical research.
iii. To identify methods for monitoring the conduct of clinical research.
iv. To review and approve reports of the Credentialing and QACS Committees

Refer to the Medical Department Organizational Chart for further illustration (ATTACHMENT B)

3.0 CRC CREDENTIALING COMMITTEE:

3.1 The Committee shall be appointed by the Chairperson of the Medical Department and consist of no less than 3 members of the CRC clinical licensed staff with the CRC Physician acting as Chairman.

3.2 The Committee shall report to the CRC Manager.

3.3 The Committee shall meet at least quarterly and have the following charge:

i. To examine the credentials, including education, training and experience of all applicants to the CRC Clinical Licensed Staff and to make recommendations to the CRC Manager and Medical Department Chairperson regarding such appointments.

ii. To evaluate and recommend specific privileges for the CRC licensed staff.

iii. To evaluate the clinical competency of Clinical Non-licensed Staff and to make recommendations regarding appointment to the CRC Manager.

iv. To assist the CRC Manager in conducting annual personnel evaluations to determine continued expertise and competency of Clinical Staff.

v. To evaluate and make recommendations to the CRC Manager and Medical Department Chairperson regarding Clinical Staff reappointment.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.2	PAGE 4 OF 1
	PREPARED BY:	
	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY

1.1 The Clinical Research Center shall operate as empowered by the Director of BNL under SPI 7-01. The reporting structure of the CRC shall reflect that stated in CRC Policy 1.1 and the Organizational Chart Attachment B.

1.2 The BNL Clinical Research Center (CRC) shall be comprised of the CRC Reception area and patient examination rooms located in the Area 8 of Building 490. CRC Satellite Facilities shall refer to other areas within Building 490 or elsewhere on site, at which clinical research, as defined under CRC Policy 2.2, is carried out. (Also see IRB manual –Clinical Research Definition)

1.3 Approved clinical research shall only take place within the CRC or its satellite facilities unless pre-approved by the CRC Manager and Medical Department Chairperson.

2.0 ORGANIZATIONAL CHART

The CRC reporting structure is illustrated by the Organizational Chart in Attachment B of this document.

3.0 CRC FACILITIES:

3.1 The CRC lobby/reception area (Building 490, Area 8-40) shall be the central point of contact for all CRC activities. The Responsible Physician shall notify the CRC Reception Desk of all studies. (See PI Manual section 5).

3.2 A satellite facility is any BNL building or area of a building which has been identified as the location where a clinical study, operating under an active (i.e. IRB approved) human protocol shall take place.

3.3 Satellite facilities of the CRC are identified in Attachment C of this document.

3.4 Each Satellite facility shall have a “Clinical Head”. The Clinical Head shall be the physician who acts as the point of contact for the facility. The Clinical Head shall be responsible for (1) the Emergency Plan; (2) insuring the facility is operating appropriately and (3) determining that individuals working in the facility are properly authorized and trained.

1.0 COMMITTEE ORIGIN:

The Chairperson of the Medical Department as part of his/her responsibility to the BNL Director for assuring an ongoing quality assurance program, shall establish the standing committee entitled "Quality Assurance, Care and Safety Committee" (QACSC).

2.0 QACSC APPOINTMENT AND MEMBERSHIP

2.1 Committee Composition:

Membership should include at least two members of the Clinical Medical Staff.
Membership should include at least one Registered Nurse, and the CRC Associate.
The Committee shall have at least four (4) other members from various areas of expertise within the CRC such as pharmacy, infection control, safety, equipment maintenance, and housekeeping.

2.2 General Terms of Appointment

The Medical Department Chairperson (during the last quarter of the fiscal year) shall appoint the members to the QACSC. The period of appointment is at the discretion of the Medical Department Chairperson. The QACSC may solicit advice and/or expertise from other CRC staff or consultants as required.

2.3 Special Appointees:

The CRC Physician shall serve as the Chairman of the QACSC.
The Clinical Medical Staff members of the QACSC shall serve as Alternative Chairman of the QACSC and shall act as Chairman in the absence of the QACSC Chairman.
The CRC Secretary shall serve as Secretary to the QACSC.

3.0 MEETING SCHEDULE AND REPORTING REQUIREMENTS

3.1 The QACSC shall meet on a monthly basis with at least ten meetings being held each calendar year.

3.2 Quorum is more than 50% of the committee members present. In addition, one (1) member of the Clinical Medical Staff must be present to reach quorum.

3.3 The Chairman of the QACSC will report to the Chairperson of the Medical Department quarterly.

3.4 The QACSC Secretary shall record minutes of each meeting. The minutes shall be distributed to Committee members to assist with task delegation and follow-up. Committee minutes shall be made available to the Medical Department Chairperson and the Advisory Committee upon its request.

4.0 DUTIES AND RESPONSIBILITIES OF THE QACSC

The duties and responsibilities of the QACSC are:

4.1 To evaluate the environment of care provided to research subjects participating in IRB-approved protocols at BNL. This shall include assessment of the safety, security, control of the medical

and hazardous wastes, emergency preparedness, life safety, utility and clinical equipment preventative maintenance plans and procedures.

4.2 To evaluate the quality, content and completeness of the medical record entries.

4.3 To assess patient satisfaction.

4.4 To assure adequate surveillance techniques that minimize sources of and transmission of infections.

4.5 To inform the BNL Institutional Review Board (IRB) of any deviation from approved research protocols noted in the course of business.

5.0 AGENDA ITEMS OF THE QASCS:

In carrying out its duties and responsibilities identified in Section 4, the Committee shall, at minimum report on the following topics:

TOPIC	PRESENTER	FREQUENCY
Reportable or Adverse Events	CRC Physician/CRC Manager	Every meeting
Infection Control	Infection Control Pract.	Every meeting
Pharmacy	Pharmacist	Quarterly
Participant Surveys	Designated Rep.	Quarterly
Preventative Maintenance	CRC Manager	Quarterly
Medical Records	CRC Physician/CRC Manager/CRA	Quarterly
Emergency Testing	Department ES&H Rep.	Quarterly
Participant Follow-up	CRC Secretary	Quarterly
Compliance of Protocol	CRC Manager/CRA	Every meeting

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.4.1	PAGE 7 OF 1
	PREPARED BY:	
SUBJECT: CRC Physician	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY

The Medical Department Chairperson, as part of his/her responsibility to the BNL Director in order to provide clinical support and oversight for studies involving human subjects, shall appoint a CRC Physician to protect the rights of subjects and promote the safety of subject and clinical staff.

2.0 QUALIFICATIONS

The CRC Physician shall have the following qualifications:

i) Be a member in good standing of the CRC Clinical Staff;
ii) Be knowledgeable of Department of Energy (DOE), National Institutes of Health (NIH), Good Clinical Practices (GCP), and Laboratory policies and procedures regarding human subject protection in clinical research and
iii) Be knowledgeable of Joint Commission on Accreditation of Healthcare Organization (JCAHO) for Ambulatory Care Facilities polices and required procedures.

3.0 REPORTING STRUCTURE

3.1 The CRC Physician reports directly to the CRC Manager.

3.2 The CRC Physician shall be reviewed annually by the Medical Department Chairperson.

4.0 CRC PHYSICIAN RESPONSIBILITIES (CRC Physician R2A2 ATTACHMENT D of this document)

The CRC Physician is responsible for:

4.1 Review all protocols concerning research in voluntary human subjects to address all issues relating to subject care.

4.2 Conduct the CRC Medical Records monitoring program

4.3 Insure the compliance of the IRB approved protocol

4.4 Providing orientation/training to new members of the CRC Clinical Medical and Courtesy Medical Staff

4.5 Determining compliance with JCAHO requirements to insure that accreditation status can be maintained

4.6 Monitoring of Adverse Event reporting

5.0 ALTERNATE TITLES AND DUTIES

The CRC Physician shall serve as Chairman of the Quality Assurance, Care and Safety Committee (QACSC) and the Credentialing Committee.

1.0 POLICY

1.1 Clinical Staff

All persons involved in human subject research who, as a result of the tasks assigned to them by the Principal Investigator, would expect to be in direct contact with the volunteer subjects, must be members of the CRC Clinical Staff. To become a member of the CRC Clinical Staff, an application must be completed and submitted to the CRC Manager.

1.2 Membership in the Clinical Staff shall be limited to those persons who are currently members of the staff of the Laboratory or otherwise authorized to participate in the Laboratory's programs. Appointment to the Laboratory's staff does not confer or imply membership in the Clinical Staff. Appointment to the Clinical Staff shall not be denied to any individual for reasons of race, sex, religion, national origin, creed, color or age.

1.3 Appointments to the CRC Clinical Staff are made by the CRC Manager, following consultation with the CRC Credentialing Committee and Medical Department Chairperson.

1.4 The professional conduct of members of the Clinical Staff are governed by:

- The Principles of Medical Ethics as currently adopted by the American Medical Association,
- The Principles of Professional Conduct of the Medical Society of the State of New York,

- The Declaration of Helsinki (Recommendation Guiding Doctors in Clinical Research adopted by the World Medical Association in 1964),
- The Federal Policy for the Protection of Human Subjects Notice and Rules (10 CFR 745),
- The Department of Energy Policy on the Protection of Human Subjects (DOE Order 1300.3), and
- The Department of Health and Human Services Rules for Protected Classes of Human Subjects (45 CFR 46)

1.5 Furthermore, each member of the Clinical Staff pledges not to directly or indirectly receive or participate in the receipt, division, transference, assignment, rebate, splitting, or refunding of a fee or receipt of gifts in connection with the furnishing of professional services to participants in the CRC.

1.6 Clinical staff shall maintain their skills through participation in a training program:

- Clinical research staff shall participate in ongoing education as provided by the department.
- Triennially, the staff will complete the "protecting study volunteers in research" self study course, or equivalent as approved by CRC manager.
- New staff and participating staff from other institutions shall complete the self-study course and review the policy and Procedure manual.

2.0 CLINICAL STAFF CATEGORIES and QUALIFICATIONS

The following classifications of Clinical Staff exist:

A. Licensed Staff:
   Physicians/Dentists-Clinical Medical Staff
   Nurses-Clinical Staff
   Other Licensed Professionals-Clinical Staff
B. Non-licensed technical staff

2.1 Licensed Staff

Physicians/Dentists - defined:
The Clinical Medical Staff is comprised of two (2) subdivisions: the Clinical Medical Staff and the Courtesy Medical Staff. Membership in the Clinical Medical Staff is conferred to BNL employees who are physicians/dentists and who apply for and are granted membership on the CRC Clinical Staff. All collaborators who are physicians/dentists having a primary affiliation at another institution and who apply for and are granted membership on the CRC Clinical Staff are considered members of the Courtesy Medical Staff.

No physician/dentist shall be entitled to membership on the Clinical Medical Staff or to the exercise of clinical privileges in the CRC merely by virtue of being duly licensed to practice medicine or dentistry in any State or province, of being a member of any professional organization, or presently or in the past having such privileges at a medical facility.

Qualifications:

a) Must have an affiliation with BNL or have an affiliation or clinical privileges at another institution;

b) Must be either:

A graduate in medicine of a medical school approved by the Council on Medical Education of the American Medical Association and licensed to practice as evidenced by licensure or permit
in a state or province of the United States or Canada, respectively. If the individual is not licensed by the State of New York (NYS) and will be practicing in NYS, the individual must be enrolled in a program which will permit NYS licensing in the future;

Or

A foreign medical graduate who possesses a valid state license or permit, or functions under an institutional permit or statute, or is in an approved training program, and, as appropriate, holds certification by the Educational Council for Foreign Medical Graduates. If the individual is not licensed by the State of New York (NYS) and will be practicing in NYS, the individual must be enrolled in a program which will permit NYS licensing in the future;

Or

A graduate of an approved or recognized dental school who is licensed to practice dentistry in a state or province of the United States or Canada, respectively. If the individual is not licensed by the State of New York (NYS) and will be practicing in NYS, the individual must be enrolled in a program which will permit NYS licensing in the future.

2.1.2 Nurses defined:

This category shall include Registered Nurses, Practical Nurses and Nurse's Aides who are, by education and training, qualified to render direct medical care under the supervision of a CRC physician.

Qualifications:

a) Be a graduate of an accredited school;
b) Possess a valid license.

2.1.3 Other Licensed Professionals defined:

This category includes Physician's Assistants/Associates (PA), Nurse Practitioners, Pharmacists, and foreign medical graduates holding certification from the Educational Council for Foreign Medical Graduates who are, by education and training, qualified to render direct medical care under the supervision of a CRC Physician.

Qualifications:

a) Be a graduate of an accredited school
b) Possess a valid license

2.2 Non Licensed Technical Staff

This category shall include any individual who, as a result of specific training and/or experience, is authorized to carry out tasks relating to human subject research within the CRC. Such tasks may include, but are not limited to: research participant recruitment, research participant screening (i.e., blood pressure, vitals, etc.) synthesis of compounds used in clinical trials, sterility and pyrogenecity procedures.

Qualifications:

a) must identify the task(s) for which they seek authorization by completing the "Clinical Competency" form (CRC Form COREC010). Such forms are obtained from the Medical Staff Office.
b) Must be evaluated by the CRC Physician or Responsible Physician as capable to perform the task(s) identified.
c) Must obtain approval from the Credentialing Committee to perform such task(s) as outlined in Section 3.5 of this manual.

3.0 APPLICATION PROCESS:

Any individual, possessing the appropriate qualifications, unquestionable integrity and moral character, who desires membership in the CRC Clinical Staff may obtain the appropriate application for membership from the Medical Staff Office.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.4.3	PAGE 11 OF 1
	PREPARED BY	
SUBJECT: CRC Manager	REVIEWED BY APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY

The Medical Department Chairperson as part of his/her responsibility to the BNL Director to provide clinical support and oversight for studies involving human subjects, will appoint, a CRC Manager to provide line management for the operation of the CRC.

2.0 BACKGROUND/QUALIFICATIONS

The CRC Manager position shall have the following qualifications:

- minimum of a bachelor degree or appropriate experience in a related field;
- knowledge of BNL and Medical Department contractual and financial policies and procedures,
- knowledge of Department of Energy, National Institutes of Health, BNL and Medical Department policies and procedures regarding human subject protection in clinical research;
- an understanding of Joint Commission on Accreditation of Healthcare Organization (JCAHO) for Ambulatory Care Facilities policies and required procedures.

3.0 REPORTING STRUCTURE

3.1 The CRC Manager reports directly to the Medical Department Chairperson

3.2 The performance of the CRC Manager shall be reviewed annually by the Medical Department Chairperson.

4.0 RESPONSIBILITIES (R2A2 ATTACHMENT E of this document)

4.1 Maintain and promulgate the policies and procedures governing the conduct of clinical (human subject) research at BNL.
4.2 Provide a process for the CRC Credentialing Committee.
4.3 Monitor the documents (Investigator files, Medical records, Case Report Forms) associated with clinical protocols to determine compliance with applicable regulations and IRB approved protocols.
4.4 Supervise the activities of the administrative support staff of the CRC.
4.5 Serve as a member of the QACSC.
4.6 Implement Adverse Event reporting procedures.
4.7 Oversee transportation of subjects and subject satisfaction.
4.8 Monitor infection control and preventative maintenance programs.
4.9 Oversee CRC Pharmacy operation.
4.10 Oversee Clinical Staff training.
4.11 Maintain currency with Federal Guidelines, JCAHO Requirements and Laboratory Policies.
4.12 Coordinate all CRC inspections, reviews and surveys.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.4.4	PAGE 12 OF 1
	PREPARED BY:	
SUBJECT: Medical Staff Office Administrator	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY

It is the policy of the CRC to maintain a central administrative point of contact to collect and maintain appropriate documentation, which supports the decisions of the CRC Credentialing Committee regarding the competencies and capabilities of the CRC Clinical Staff. The Medical Staff Office Administrator is designated as the point of contact.

2.0 QUALIFICATIONS

The Medical Staff Office Administrator shall have the following qualifications:

- a degree in Secretarial Science, or comparable experience, preferable with a medical or hospital administration concentration ;
- familiarity with BNL, Medical Department and CRC policies and procedures;

- knowledge of Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and
  requirements;
- knowledge of applicable DOE, NIH and GCP regulations regarding clinical studies;
- excellent organizational skills;
- the ability to coordinate multiple tasks and perform follow-up required completing complex tasks.

3.0 RESPONSIBILITIES

3.1 The Medical Staff Office Administrator shall report to the CRC Manager.

3.2 The Medical Staff Office Administrator shall have the following duties and responsibilities:

- Serve as Secretary of the CRC Credientialing and QACSC Committees;
- Coordinate the application process for individuals desiring membership on the CRC Clinical Staff;
- Collect documentation and perform prime source verification of information required by the Credentialing Committee for its review and evaluation of an applicant's request to join the CRC Clinical Staff;
- Maintain the CRC Clinical Staff files, including sending letters of request to obtain, as applicable, license renewals, infection control re-certifications, TB form and Blood Borne Pathogen Training re-certifications;
- Inform CRC Clinical Staff members when current appointments are due to expire and coordinate the reapplication process; and
- Maintain documentation with supporting designations of Responsible Physician and Participating Physician for each active IRB protocol.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.4.5	PAGE 1 OF 1
	PREPARED BY:	
SUBJECT: Infection Control Practitioner	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY

It is the policy of the CRC to make the best efforts to identify and subsequently reduce the risk of acquiring and transmitting infectious diseases. This effort shall be an organization-wide coordinated process managed by a designated individual, the Infection Control Practitioner.

The Infection Control Practitioner shall be responsible for planning, directing and coordinating the Infection Control Program of the CRC and its satellite facilities in an effort to reduce the risks associated with the transmission of infectious agents and to improve the health outcomes of clinical subjects and the CRC staff.

2.0 BACKGROUND/QUALIFICATIONS

The Infection Control Practitioner shall have the following qualifications:

- a degree, certification or license in epidemiology, medicine, medical technology, microbiology, nursing, or another health-related discipline;
- willingness to obtain membership in appropriate professional organizations and to participate in professional development and continuing education seminars and workshops; and an understanding of Joint Commission on Accreditation of Healthcare Organization (JCAHO) for Ambulatory Care Facilities polices and required procedures.

3.0 REPORTING STRUCTURE

The Infection Control Practitioner shall report directly to the CRC Manager.

4.0 INFECTION CONTROL PRACTITIONER RESPONSIBILITIES

4.1 Performing surveillance of the clinical facilities.
4.2 Reporting infection control issues to the appropriate PI and CRC manager
4.3 Participating in continuing education courses to keep current on infection control practices and guidelines.
4.4 Conducting in-service training sessions for clinical staff.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	NUMBER: CRC 1.4.6	PAGE 14 OF 1
	PREPARED BY:	
SUBJECT: CRC Secretary/Receptionist	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY
It is the policy of the CRC to maintain a single administrative point of contact for all CRC activities and participant issues. The CRC Receptionist and/ or Secretary is designated as the point of contact.

2.0 QUALIFICATIONS
The CRC Receptionist or Secretary shall have the following qualifications:
- an AAS degree in Secretarial Science, preferably with a medical concentration (or comparable experience).
- familiarity with BNL, Medical Department and CRC policies and procedures;
- organizational skills necessary to coordinate several studies simultaneously;
- an ability to maintain a warm and caring environment for participants; and
- good judgment in order to protect participants' rights, including privacy and confidentiality.

3.0 RESPONSIBILITIES
3.1 The CRC Secretary/Receptionist shall report to the CRC Manager.

3.2 The CRC Receptionist and/or Secretary shall have the following duties:
- Coordinate the daily schedules for clinical programs operating within the CRC;
- Notify participants regarding date and time of study;
- Coordinate participant transportation to/from and within the CRC;
- Remuneration, through the BNL Fiscal system, of clinical subjects, as provided by specific clinical protocols (CIRCs);
- Provide each subject with a "Participant Rights" pamphlets at the CRC desk;
- Distribute a "Patient-Donor, Your Comments and Suggestions" (Participant Survey) form;
- Maintain and update all CRC Forms, as instructed by the CRC Manager;
- Assemble Medical Record (chart) in accordance the IRB approved protocols;
-Maintain control logs and/or files (i.e. the Daily Participant Log, the Participant index file card/database, Medical Record Control Log, etc.) as required by CRC Policy or as instructed by the CRC Manager;
- Report to the CRC Manager or CRC Physician any incident noted which involved a participant's disatisfaction or a breach of CRC Policy;
- Act as coordinator in the event of a CRC emergency;
- Provide clerical and administrative support to the CRC staff;
- Serve as the Secretary to the Quality Assurance, Care and Safety Committee; and
- On an annual basis, distribute and follow-up to assure that all standing orders are updated by the Responsible Physician.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	NUMBER: CRC 1.4.7	PAGE 14 OF 1
	PREPARED BY:	
SUBJECT: Medical/Hospital Services Assistant	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY
It is the policy of the CRC to maintain centralized clinical support staff (Medical Service Assistant(s)) who are available to support the Professional and research staff at BNL in the performance of clinical studies.

2.0 QUALIFICATIONS

2.1 Medical Service Assistant shall have the following qualifications:

- possess training and certification as a Nurses' Aide, or comparable work experience;
- possess appropriate BNL training, including Blood Borne Pathogens and Radiation Worker training;
- be familiar with BNL, Medical Department and CRC policies and procedures;
- exhibit excellent patient care skills and maintain a warm and caring environment for participants;
- possess physical dexterity and be in good physical health in order to assist participants as necessary;
  and
- be knowledgeable of infection control protocols.

3.0 RESPONSIBILITIES

3.1 The Medical/Hospital Services Assistant shall report to the CRC Manager.

3.2 The Medical Service Assistant shall perform the following duties:

- perform housekeeping tasks for the CRC and satellite facilities;
- transport medical records and/or supplies for clinical studies to/from satellite facilities,
- assist with clinical protocols, as directed by the Responsible Physician or his/her delegate;
- collect, transport and package regulated medical waste;
- order and stock medical supplies, as instructed by the CRC Medical Staff;
- coordinate the collection of dirty laundry and maintain clean laundry; and
- back-up the CRC Secretary/Receptionist, as needed.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	NUMBER: CRC 1.4.8	PAGE 15 OF 1
	PREPARED BY:	
SUBJECT: CRC Equipment Technician	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY
It is the policy of the CRC to insure that all equipment and devices used during clinical studies are safe and in good working condition to effect a safe environment and reliable data.

2.0 QUALIFICATIONS
The CRC Equipment Technician shall have the following qualifications:

- experience with electronic equipment, including troubleshooting, repair and maintenance;
- familiarity with hospital/clinical equipment; and
- knowledge of Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and requirements regarding preventive maintenance.

3.0 RESPONSIBILITIES

3.1 Carry out the CRC preventative maintenance program as described at Section 6.8 of this manual.
3.2 Perform repairs to CRC equipment as requested.

4.0 REPORTING STRUCTURE
The CRC Equipment Technician shall be responsible to the CRC Manager.

BROOKHAVEN NATIONAL LABORATORY CLINCICAL RESEARCH CENTER POLICY	NUMBER: CRC 1.4.9	PAGE 16 OF 1
	PREPARED BY:	
SUBJECT: CRC Pharmacist	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY
The CRC shall have a Pharmacist who is responsible for the operations of the CRC Pharmacy.

2.0 QUALIFICATIONS
The CRC Pharmacist shall have the following qualifications:

- a valid New York State license to practice Pharmacy; and
- knowledge and experience as a pharmacist in a research institution or hospital.

3.0 **RESPONSIBILITIES**
The CRC Pharmacist shall be responsible for:

3.1 Ordering, receiving, dispensing and storing pharmaceuticals, including controlled substances, associated with on-going clinical and research protocols;
3.2 Conducting periodic inventories of satellite pharmacy (storage) locations and reporting the results of such procedures to the CRC Manager;
3.3 Maintain pharmaceuticals in the crash carts located within the CRC and its satellite facilities;
3.4 Performing administrative tasks associated with a Registered Pharmacy as required by New York State, the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA).

4.0 REPORTING STRUCTURE
The CRC Pharmacist shall be responsible to the CRC Manager.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	NUMBER: CRC 1.4.10	PAGE 16 OF 1
	PREPARED BY:	
SUBJECT: Clinical Research Associate (CRA)	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY
It is the policy of the CRC to have a Clinical Research Associate (CRA) who will provide technical and regulatory information and support to the Principal Investigators.

2.0 QUALIFICATIONS
The CRA shall have the following qualifications:

2.1 Must obtain or be a Certified Clinical Research Associate (CCRA) or Certified Clinical Research Coordinator (CCRC).

2.1 Must have a knowledge of Good Clinical Practices (GCP) and other federal regulations.

2.2 Must have knowledge of monitoring and maintaining study documents (i.e. Case Report Forms, (CRF), source documents, Investigator files and research protocols.

2.3 Must have a knowledge of Adverse Events (AE), Informed Consent and IRB regulatory issues.

3.0 RESPONSIBILITIES (R2A2 ATTACHMENT F)

The Clinical Research Associate (CRA) shall be responsible for:

3.1 Review and approve initial forms for each protocol that has been developed by the PI or RP and upon this approval notify the CRC Manager.

3.2 Review regulatory requirements annually and make recommendations to the PI/RP to ensure regulatory compliance.

3.3 Assist in the preparation of the package to be submitted to the IRB for annual review (including subject accrual reconciliation).

3.4 Assist in the continuous review of investigator files and medical records.

3.5 Report to the PI concerning any problems in record keeping or protocol compliance.

3.6 Provide periodic reports to the CRC Manager and Medical Department Chairperson regarding overall conduct of clinical research and issues relating to adherence to applicable regulations.

4.0 REPORTING STRUCTURE

The Clinical Research Associate shall be accessible to the PIs and will be responsible to the Medical Department Chairperson.

BROOKHAVEN NATIONAL LABORATORY CLINICAL RESEARCH CENTER POLICY	CRC POLICY 1.5.1	PAGE 17 OF 1
	PREPARED BY:	
SUBJECT: CRC Facility and Satellite Facilities - Defined	REVIEWED BY:	
	APPROVED BY:	
	EFFECTIVE DATE:	

1.0 POLICY:

The BNL Clinical Research Center (CRC) shall be comprised of the CRC Reception area and adjoining patient examination rooms located in Area 8 of Building 490. CRC Satellite Facilities shall refer to other areas within Building 490 or other locations where clinical research, as defined under CRC Policy 2.2, is carried out.

Approved clinical research shall only take place within the CRC or its satellite facilities unless specific pre-approval is obtained from the CRC Manager and the Medical Department Chairperson.

Facilities of the CRC are identified in ATTACHMENT C of this document.

2.0 IDENTIFICATION OF CRC SATELLITE FACILITIES:

2.1 A satellite facility is any BNL building or area of a building which has been identified as the location where a clinical study, operating under an active (i.e. IRB approved) human protocol shall take place.

2.2 Each Satellite facility shall have a "Clinical Head". The Clinical Head shall be a physician who acts as the point of contact for the facility. The Clinical Head shall be responsible for (1) the Emergency Plan; (2) insuring the facility is operating appropriately and (3) determining that individuals working in the facility are properly authorized and trained.

CRC FACILITY DESCRIPTION	LOCATION	MAIN TELEPHONE EXTENSION	CLINICAL HEAD/RESPONSIBLE PHYSICIAN	DRILL COORDIN/
CRC RECEPTION AREA	Bldg 490 CRC Lobby; Exam RMS (8-33 & 8-32). Office (8-34)	X-3672	CRC PHYSICIAN	R. COLICH
CRC PHARMACY	BLDG 490, RM 5-4	X-3589	G.J. WANG	N/A
MRI FACILITY	BLDG 560	X-6267	J. PAN	J. LEE
PET FACILITY	BLDG 906	X-8032	G.J. WANG	N PAPPAS
PULMANANY LABORATORY	BLDG 490, RM 9-131	X-3611	D. FRANCESCHI	R. COLICH
TOSHIBA SPECT FACILITY	BLDG 490, RM	X-5153	H.L. ATKINS	R. COLICH
WHOLE BODY COMPOSITION FACILITIES	WHOLE BODY COMP (5-9); CARBON ROOM (5-305); PROMPT GAMMA (9-424)	X-3658 X-3688 X-3681	H.L ATKINS	R. COLICH

ATTACHMENT D
CRC POLICY 1.4.1

R2A2 CLINICAL RESEARCH CENTER (CRC) PHYSICIAN

Roles:

- To contribute to the establishment and maintenance of an environment for research involving human subjects which protects the rights of subjects and promotes safety for subjects and clinical staff.

Responsibilities:

- Chair the CRC Credentialing Committee to credential physicians, nurses and other clinical research staff who have contact with subjects
- Conduct the CRC protocol compliance monitoring program
- Review all protocols concerning research in voluntary human subjects to address all issues relating to subject care

Accountabilities:

- To the CRC Manager and the Chair of the Medical Department for performances of above tasks.

Authorities:

- Stop or interrupt a clinical study upon evidence of a hazard for the safety and/or rights for subject

R2A2 CLINICAL RESEARCH CENTER (CRC) MANAGER

Role

- To provide line management for the operation of the CRC.

Responsibilities

- Oversee day to day operation of the Clinical Research Center to insure human subject safety and Investigator/Staff compliance with existing policies and regulations.
- Maintain the CRC Principal Investigator's Manual
- Implement adverse event reporting procedures
- Establish procedures to be implemented by the Credentialing Committee for credentialing of physicians, nurses, and other clinical research staff who have contact with subjects under a protocol
- Implement procedures for the preparation and maintenance of medical records using protocol specific forms generated by the PI/RP
- Implement procedures for the scheduling and transportation of subjects and registering subjects upon arrival at BNL
- Maintain a program for monitoring infection control at all BNL sites where clinical research is conducted
- Maintain a program for preventive maintenance of all equipment used in clinical research that is not a component of the research facility itself
- Implement procedures for the operation of the CRC Pharmacy including a controlled substance monitoring program
- Establish and implement a medical records monitoring program that requires at least monthly random review of medical records for accuracy and completeness
- Establish and implement a protocol compliance monitoring program that requires at least semi-annual random review of investigator files and medical records to determine if approved protocol has been followed
- Establish and implement a program to assess subject satisfaction
- Review JCAHO requirements annually and make recommendations to Medical Department Chair for compliance
- Maintain and revise CRC policy and procedural guidelines and present such to the Medical Department Chair for review and approval.
- Participate as a member of the CRC Quality Assurance, Care and Safety Committee.

- Advise Clinical Investigators of regulations and/or requirements of proposed and approved clinical studies.
- Conduct the CRC medical records monitoring program
- Develop, organize and schedule staff training on clinical research issues and topics.
- Coordinate and/or participate in various audits and surveys on BNL's clinical research programs
- Coordinate the triennial JCAHO accreditation survey.

ATTACHMENT E
CRC POLICY 1.4.3

Accountabilities
- To the Chair of the Medical Department and Laboratory management for performance of the above tasks.
- To the subjects and CRC staff, to create an environment wherein subjects' rights and individual safety are the primary focus.
- To the Medical Department Chair to inform him/her of issues of non-compliance with CRC operating policy and procedure.
- To the PI's, to advise them regarding applicable Federal regulations and BNL policies.

Authorities
- Allocate CRC resources as appropriate.
- Stop or interrupt a clinical study upon evidence of a hazard to the safety and/or rights of a human subject.
- Implement procedures consistent with Federal guidelines and BNL CRC Policies to promote the safety and rights of human subjects participating in clinical protocols.

ATTACHMENT F
CRC POLICY 1.4.10

R2A2 CLINICAL RESEARCH ASSOCIATE

Clinical Research Associate (CRA)

Role
- Provide technical and regulatory information and support to the Principal Investigators carrying out Human Studies

Responsibilities
- Review and approve initial forms for each protocol that have been developed by the Principal Investigator and Responsible Physician

- Review regulatory requirements annually and make recommendations to the Principal Investigator/Responsible Physician to ensure regulatory compliance
- Assist in the preparation of the package to be submitted to the IRB for annual review (including subject accrual reconciliation)
- Assist in the continuous review of investigator files and medical records
- Report to the Principal Investigator any problems in record keeping or protocol compliance

Accountability

- To the Principal Investigator for performance of the above tasks
- To the Chair of the Medical Department for assisting the Principal Investigator in carrying out Human Studies Research

Authorities

- To take action needed to ensure that Human Studies Research is carried out in compliance with regulatory policies